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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,543	07/27/2001	Konrad Basler	Q-60361	9256

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EXAMINER	
LACOURCIERE, KAREN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/915,543	BASLER ET AL.	
	Examiner	Art Unit	
	Karen A. Lacourciere	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 28 September 2003.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 71-78 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 71-78 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

The Objection to the Abstract set forth in the prior Office action (mailed 03-11-2003) is withdrawn in response to Applicant's amendments filed 09-11-03, which provides a substitute Abstract.

Response to Amendment

The rejections of record set forth in the prior Office action (mailed 03-11-2003) are rendered moot because Applicant has canceled all claims pending at the time of said Office action, however, new rejections are set forth as follows, in response to newly added claims 71-78.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 71-78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 71-78 are drawn to encompass polypeptides comprising a sequence consisting of residues 177-204 or residues 349-383 or residues 199-392 of SEQ ID NO:15, polypeptides comprising a sequence 90% identical to said sequences or

polypeptides comprising a fragment of any of the afore mentioned polypeptides wherein the fragment encompasses a binding site for generally any anti-Bc19/hLgs antibody. The specification discloses SEQ ID NO: 15 and 17, which correspond to the human BCL9 and lgs-1 proteins and SEQ ID NO:10, which corresponds to the drosophila lgs protein, which are species that fall within the scope of the claimed invention because they comprise the claimed homology regions (residues 177-204 or residues 349-383 or residues 199-392 of SEQ ID NO:15). SEQ ID NO: 10, 15 and 17 and polypeptides consisting of residues 177-204, residues 349-383 or residues 199-392 of SEQ ID NO:15, meet the written description provisions of 35 USC 112, first paragraph, however, claims 71-78 are directed to encompass a much broader genus of polypeptides wherein the polypeptide comprises any one of the small homology regions specified. Each of the specifically claimed homology regions is a small peptide sequence comprised within a much larger polypeptide (e.g. each of these regions is a 28 amino acid sequence or 35 amino acid sequence comprised within the a full length polypeptide which is more than 1400 amino acids residues long). The claimed polypeptides encompass a large genus of polypeptide sequences comprising residues 177-204 or residues 349-383 or residues 199-392 of SEQ ID NO:15, including full length polypeptides from other species, mutated versions of the full length polypeptide, polypeptides encoded by allelic variants and splice variants, derivatives and variants of these polypeptides, polypeptides comprising a fragment of unspecified length (e.g. even one amino acid residue of residues 199-392 of SEQ ID NO:15) wherein there is a common epitope with Bc19/hLgs and so forth. None of these amino acid sequences meet the written

description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the very broad genus of polypeptides encompassed by the claim. For example, polypeptides comprising a fragment of residues 199-392 of SEQ ID NO:15, wherein the fragment comprises a binding site for an anti-Bc19/hLgs antibody would encompass polypeptides with a little as one amino acid in common with the species described by the specification.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 10, 15, and 17 and polypeptides consisting of residues 177-204, residues 349-383 or residues 199-392 of SEQ ID NO:15, the skilled artisan cannot envision the detailed chemical structure of the encompassed proteins (or polynucleotides encoding such), regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypeptide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.
>
> An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.
>
> The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 10, 15 and 17 and polypeptides consisting of residues 177-204, residues 349-383 or residues 199-392 of SEQ ID NO:15, but not the full breadth of the claim, meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear

that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-16, 20, 21, 23, 24, 44 and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by Tang et al. (WO 01/57188).

Tang et al. disclose, and claim, an isolated polypeptide (SEQ ID NO: 2178 of Tang et al.) that is 99.4% identical to amino acid residues 1-1392 of the instantly disclosed human lgs/BCL9 protein (97% identical to the full length) (SEQ ID NO: 15 of the instant application) (see sequence alignment attached to the prior Office action mailed 03-11-2003), wherein the polypeptide comprises residues 177-204, residues 349-383 and residues 199-392 of SEQ ID NO:15 and wherein the polypeptide comprises a fragment comprises a binding site for an anti-Bc19/hLgs antibody . Tang et al. disclose their polypeptide as a chimeric protein, fused to a heterologous amino acid sequence (see for example pages 27-34), including, for example, a GST moiety, a thioredoxin moiety, an antibody moiety and an epitope tag sequence (see for example page 31). Tang et al. disclose their polypeptide in a pharmaceutical composition, including wherein the protein is in a carrier facilitating the transport of the protein across a cell membrane (see for example, section 4.12.2 Compositions/Formulations). Tang et al. do not disclose their protein as blocking Lgs function in colon cancer cells, however,

they disclose their protein as a human BCL9 homologue and their protein meets all of the physical limitations of the claims and their protein is 97% identical (99.4% identical to residues 1-1392) to one embodiment of the claimed invention disclosed in the instant specification and further comprises the specific homology regions claimed and, therefore, would be expected to block Lgs function, as claimed.

Therefore, Tang et al. (WO 01/57188) anticipates claims 71-78.

Response to Arguments

Applicant's arguments filed 09-11-2003 have been fully considered but they are not persuasive. Applicant provides arguments directed to the rejections of record set forth in the prior Office action, mailed 03-11-2003, these rejections have been withdrawn in response to the cancellation of all claims considered on the merits during the preparation of the last Office action, however, these arguments have been considered to the extent they read on the rejections of claim 71-78 set forth herein, but they have not been found persuasive.

Applicant argues that the newly submitted claims are not subject to the rejection under 35 USC 102(e) as anticipated by Tang et al. because claims 71-78 are directed to isolated polypeptides comprises peptide fragments of SEQ ID NO:15 and that the peptide disclosed by Tang et al. does not block Lgs function in colon cancer cells as evidenced by the experiment in Figure 15 B of the instant specification which is used as the positive control (see page 10 of the arguments filed 09-011-2003). This is not found to be persuasive because the polypeptide disclosed by Tang et al. does comprise the specifically claimed fragments and further, the experiment conducted in Figure 15B

does not appear to use the polypeptide of Tang et al. as a positive control, as Applicant's arguments assert. The figure legend of Figure 15 (see pages 19-20 of the instant specification), which cites Roose et al. as the peptide used as a positive control. Figure 15 B makes no reference at all to the polypeptide disclosed by Tang et al. and it is unclear how this experiment provides any evidence related to the function of the polypeptide disclosed by Tang etal. Further, the experiment disclosed in 15B examines luciferase expression as one measure of Lgs function. The limitation Lgs function is very broad and encompasses many functions, beyond the one function examined by the experiment of Figure 15 B of the instant specification. Given the very close identity of the polypeptide disclosed by Tang et al. to the physical characteristics of the claimed polypeptides and the preferred embodiment of the polypeptide disclosed in the specification, it would be expected that the polypeptide disclosed by Tang et al. would block a function of Lgs in colon cancer cells.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Lacourciere whose telephone number is (703) 308-7523. The examiner can normally be reached on Monday-Thursday 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-1935 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Karen A. Lacourciere
November 20, 2003

KAREN A. LACOURCIERE, PH.D.
PRIMARY EXAMINER